Complete Summary

GUIDELINE TITLE

Recommendations for the diagnosis and management of recurrent aphthous stomatitis.

BIBLIOGRAPHIC SOURCE(S)

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Recommendations for the diagnosis and management of recurrent aphthous stomatitis. Austin (TX): University of Texas at Austin, School of Nursing; 2003 May. 12 p. [24 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 2, 2007, Colchicine: Immediate drug recall for all strengths, sizes and lots of ApothéCure compounded injectable Colchicine sold within the last year due to recent deaths associated with the use of the product.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Minor, major, and severe recurrent aphthous stomatitis (canker sores)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dentistry
Family Practice
Nursing
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Dentists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis and management of recurrent aphthous stomatitis

TARGET POPULATION

General population of all ages afflicted with minor, major, or severe recurrent aphthous stomatitis (RAS)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Subjective assessment, including current history, past medical history and family medical history
2. Physical examination
3. Diagnostic tests as indicated
4. Classification of ulcers as mild, moderate, or severe

Management/Treatment

1. Non-pharmacological therapy (e.g., oral hygiene, trauma prevention, avoidance of certain foods/drinks, use of straws, relaxation techniques)
2. Pharmacological therapy for minor to major recurrent aphthous stomatitis:
    - Over-the-counter conservative treatment
        - liquid antacids or 3% hydrogen peroxide/water solution
    - Covering agents/topical analgesics/anesthetics/numbing agents/anti-inflammatory
        - Orabase, Benzydamine hydrochloride (HCL) mouthwash
        - Diphenhydramine EMLA alone or mixed with Kaopectate or aluminum hydroxide, or Maalox
        - Viscous Lidocaine 1:1 with Benadryl plus Maalox
        - Aphthasol 5% (amlexanox)
    - Antiseptic mouthwashes
        - Benzydamine hydrochloride (Difflam)
        - Chlorhexadine gluconate [Peridex/Corsodyl]
        - Carboxymethylcellulose paste (Orabase)
    - Low potency topical steroid pellets and ointments
        - Triamcinolone 0.1% in carboxymethylcellulose paste (Adcortyl in Orabase) & Triamcinolone acetonide (Kenalog in Orabase)
        - Hydrocortisone sodium succinate (Corlan)
    - Aerosols
        - Beclomethasone dipropionate aerosol (Beconase spray)
    - Steroid mouthwashes
        - Betamethasone sodium phosphate (Betnesol mouthwash/Diprolene)
        - Fluocinonide (Lidex), clobetasol (Temovate)
3. Pharmacological therapy for severe aphthous stomatitis
    - Systemic drugs
        - Oral prednisolone
        - Thalidomide
        - Colchicines or Pentoxifylline
        - Azathioprine
    - Tetracycline (capsules and/or topical)
    - Topical immunomodulatory agents (azelastine, human alpha-2 interferon cream, topical cyclosporine, deglycyrrhizinated licorice, topical 5-aminosalicylic acid [5-ASA], amlexanox 5% paste, prostaglandin E2 [PGE2])
4. Pharmacologic therapy for children under age 12
    - First line treatment
        - Benzydamine and local anesthetics
        - Lidocaine gel preps [Calgel teething gel])
    - In more severe cases
        - Triamcinolone 0.1% in carboxymethylcellulose paste (Adcortyl in Orabase)
        - Hydrocortisone sodium succinate (Corlan)
5. Treatment for HIV-associated ulcers
    - Antifungal treatment in conjunction with steroids
    - Biopsy
6. Patient education
7. Follow-up
8. Referral to or consultation with specialist as indicated

MAJOR OUTCOMES CONSIDERED

- Rate of pain resolution
- Rate of healing
- Rate of occurrence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature was searched through PubMed, Medline, EBSCO, CINAHL, Science Direct, OVID, Med-Connections, USDHHS and UTNetCat and clinical textbooks. The electronic search included current literature (after 1996) as well as literature dated before 1994 but retrieved in 2003 with continued relevant evidence of treatment guidelines, and research studies.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of the Evidence

- Category Ia. Evidence is obtained from meta-analysis of randomized controlled trials.
- Category Ib. Evidence is obtained from at least one randomized controlled trial.
- Category IIa. Evidence is obtained from at least one well-designed controlled study without randomization.
- Category IIb. Evidence is obtained from at least one other type of well-designed quasi-experimental study.
- Category III. Evidence is obtained from well-designed non-experimental descriptive studies such as comparative studies, correlational studies, and case control studies.
- Category IV. Evidence is obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Adapted from: United Stated Department of Health and Human Services (U.S. DHHS), Office of Public Health & Science. U.S. Preventive Services Task Force, (1996). Guideline to Clinical Preventive Services, (2nd ed.), Alexandria, VA: International Medical Publishing, Inc.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of the recommendation

A. There is good evidence to support the recommendation that the treatment be specifically considered in the management of recurrent aphthous stomatitis.
B. There is fair evidence to support the recommendation that the treatment be specifically considered in the management of recurrent aphthous stomatitis.
C. There is insufficient evidence to recommend for or against the inclusion of the treatment in the management of recurrent aphthous stomatitis, but recommendations may be made on other grounds.
D. There is fair evidence to support the recommendation that the treatment be excluded from consideration in the management of recurrent aphthous stomatitis.
E. There is good evidence to support the recommendation that the treatment be excluded from consideration in the management of recurrent aphthous stomatitis.

Adapted from: United Stated Department of Health and Human Services (U.S. DHHS), Office of Public Health & Science. U.S. Preventive Services Task Force, (1996). Guideline to Clinical Preventive Services, (2nd ed.), Alexandria, VA: International Medical Publishing, Inc.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft of the guideline was developed by a team of Family Nurse Practitioner students and submitted for review to faculty of the Family Nurse Practitioner program. Revisions were made after recommendations were received. An outside specialist provided final external review.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Grades of the evidence definitions (I-a, I-b, II-a, II-b, III, IV) and strength of the recommendations (A-E) are repeated at the end of the major recommendations field.

Diagnosis/Evaluation

- Complete comprehensive history of present illness, severity, frequency, duration, associated weight loss or decreased appetite, and past treatments and response.
- Focused exam of lips, mucous membranes and buccal mucosa, dentition, and bite alignment. Sores are typically found in the movable parts of the mouth (i.e., the tongue or the inside linings of the lips and cheeks). Refer to the original guideline document for a table describing classification of ulcers.
- Differential diagnoses include herpetic gingival stomatitis, herpangina, hand foot and mouth disease, bullous diseases, lichen planus, Reiter's syndrome, squamous cell carcinoma, Behcet's disease, adverse drug reactions such as chemotherapy, gold fillings, fixed eruption, immunosuppression, neutropenia, and celiac disease. Complex aphthous and complex aphthous variants associated with systemic disorders should be considered. See the original guideline document for a table with further description of differential diagnosis.
- Diagnostic tests usually are not ordered. If suspected nutritional deficiency, B12, folate/iron levels, and complete blood count (CBC) with differential may be considered. Tzanck smear to rule out herpetic stomatitis, human immunodeficiency virus (HIV) testing for large and slow healing ulcers, and biopsy may be needed for suspected cancer (strength of recommendation A; quality of evidence III & IV).
- Principles of treatment include:
    - May need several treatments before they find one that works well for them.
    - Initial treatment goals include decreasing the number of ulcers, decreasing pain, and at times reducing frequency.
    - In more severe cases, the treatment goal for most people is decreasing pain, trying to make the ulcers more bearable (strength of recommendation B; quality of evidence III).

Treatment/Management

- Lifestyle modifications may aid in prevention, decreased frequency of sores, or minimizing discomfort. Modifications include practicing good oral hygiene,

preventing trauma by using adequate sized toothbrush, instituting relaxation techniques to minimize stress, drinking through straw, and avoiding acidic beverages and spicy or sharp/crispy foods, such as chips (strength of recommendation B; quality of evidence III).

- Non-pharmacological treatments include good oral hygiene, prevention of trauma (adequate sized toothbrush), avoidance of spicy foods and acidic fruit juices or carbonated drinks, drinking through a straw to bypass the mouth, avoiding sharp foods such as crisps, avoiding stress if possible which may exacerbate ulcers or trigger a series of ulcers, and orthodontist referral. In addition, if vitamin deficiency has been diagnosed, this should be treated and corrected; if food allergies have been determined, these foods should be avoided (strength of recommendation B; quality of evidence IV)

Pharmacological therapy for minor and major recurrent aphthous stomatitis

- Pharmacological treatment options include vitamins and nutritional supplements, topical glucocorticoids, topical anesthetics, and systemic medications. First line treatment for minor and major recurrent aphthous stomatitis are listed in Table 1.
- Follow up in 1 to 2 days for infants and elderly persons not taking fluids (Strength of recommendation A, quality of evidence III).

Table 1: Treatment regimens minor to major recurrent aphthous ulcers

Type of treatment	Preparations	Particularly suitable for
Over-the-counter conservative treatment	Liquid antacids or 3% hydrogen peroxide/water solution, 1:1 as a gargle (Strength of recommendation B, quality of evidence IV)	Minor recurrent apthous ulcer (AU).
Covering agents/topical analgesics/anesthetics/numbing agents/anti-inflammatory	1. Orabase, Benzydamine hydrochloride (HCL) mouthwash 2. Diphenhydramine EMLA, or mixed 1:1 with Kaopectate or aluminum hydroxide, or Maalox 3. Viscous lidocaine 1:1 with Benadryl plus Maalox 4. Aphthasol 5%(amlexanox) paste, apply over canker sore, forms a film which protects canker sore	Single, sporadic, infrequent minor or major ulcers. Accelerate resolution of pain and healing, have not been shown to reduce the rate of occurrence

Type of treatment	Preparations	Particularly suitable for
	and delivers medication, four times daily (QID), after meals and at bedtime (HS). (Strength of recommendation A, quality of evidence II a)	
Antiseptic mouthwashes	1. Benzydamine hydrochloride (Difflam), at least three times daily (TID) 2. Chlorhexadine gluconate (Peridex/Corsodyl) at least TID 3. Carboxymethylcellulose paste (Orabase) (Strength of recommendation A, quality of evidence III).	Antibacterial mouthwashes. Primarily for reduction of pain and with wide range of oral sites not accessible to covering pastes, also speed up healing
Low potency topical steroid pellets and Ointments	1. Triamcinolone 0.1% in carboxymethylcellulose paste (Adcortyl in Orabase) & Triamcinolone acetonide (Kenalog in Orabase), qid to dried areas around ulcers with moistened finger. Allow film to hydrate before allowing contact with uninvolved mucosa, one application last thing at HS (minor AU). 2. Hydrocortisone sodium succinate 2.5mg (Corlan) qid during attack, bid between attacks for at least 6 weeks before reducing to use during attacks only (minor AU) (use of steroids is consensus effective treatment from	Anti-inflammatory agents. Frequently recurring mild ulcers or major ulcers. Steroids may be used to reduce the frequency of attacks. Most successful with ulcers located in the sulci where pellet can be left to dissolve.

Type of treatment	Preparations	Particularly suitable for
	almost all sources). (Strength of recommendation A, quality of evidence III, & IV)	
Aerosols	1. Beclomethasone dipropionate aerosol (Beconase spray) 2 puffs (100 micrograms) spray onto affected mucosa to a max of 8 puffs/day. Reduced risks of adverse effects over Betamethasone mouthwash but slightly less effective. Useful if only one or two ulcers are present (moderately severe). (Strength of recommendation A, quality of evidence IV)	Most useful when more potent steroid needed and for inaccessible sites (i.e., soft palate or oropharynx).
Steroid mouthwashes	1. Betamethasone sodium phosphate (Betnesol mouthwash/Diprolene) one 0.5mg tablet dissolved in 5 to 10 ml of water used as a mouthwash qid during ulcer attack. Must be held in mouth for a minimum of 3 minutes for maximum effectiveness; spit out after use. Can be used 6 times a day under strict supervision (strength of recommendation A, quality evidence III) 2. Fluocinonide (Lidex), clobetasol (Temovate) same as Betamethasone (same recommendation &	Useful with wide range of ulcer sites and of sufficient severity to merit therapeutic treatment. Monitoring for side effects of steroids is essential as some medication always gets swallowed inadvertently.

Type of treatment	Preparations	Particularly suitable for
	quality)	

Pharmacological therapy for severe, recurrent aphthous ulcers

- Treatment recommendations for severe recurrent aphthous ulcers are listed in Table 2.
- Follow up in severe cases in 2 to 3 days (strength of evidence A, quality of evidence III).
- Consult specialist if not healed in 2 to 3 weeks.

Table 2: Treatment regimens for severe, recurrent aphthous ulcers

Type of treatment	Preparations	Particularly suitable for
Systemic drugs	1. Oral prednisolone 40 mg for 5 days, reduce by 5 mg every 2 days to 5 mg, reduce by 1 mg/day until complete. Monitor severity closely at 15 mg dos; select maintenance dose to maintain remission before ulcers reappear (strength of recommendation B, quality evidence IV) 2. Thalidomide 200 mg qd or bid 3 to 8 weeks for HIV or Behcet's disease severe AU (strength of recommendation D, quality of evidence IV – restricted use in U.S.) 3. Colchicines 500 micrograms/day or Pentoxifylline 400 mg tid (strength of recommendation C, quality of evidence IV) 4. Azathioprine 50 to 100mg daily primarily as a steroid sparing agent during maintenance phase of treatment (strength of	Reserved for severe recurrent aphthous ulcers interfering with nutrition.

Type of treatment	Preparations	Particularly suitable for
	recommendation B, quality of evidence III).	
Tetracycline	1. Tetracycline 250-mg capsules dissolved in 10 ml of water and used as a mouthwash. Gargle for 3 minutes then spit out (strength of recommendation B, quality of evidence III). 2. Topical tetracycline (aureomycin, chlortetracycline, and tetracycline) (strength of recommendation B, quality of evidence IIII & IV)	Herpetiform ulcers. Often unresponsive to steroids, which form a second line of treatment if tetracyclines fail.
Topical immunomodulatory agents	Azelastine, human alpha-2 interferon cream, topical cyclosporine, deglycyrrhizinated licorice, topical 5-aminosalicylic acid (5-ASA), amlexanox 5% paste, and prostaglandin E2 (PGE2) gel. (Strength of recommendation C, quality of evidence IV).	Suggested to be of some benefit in the management of recurrent aphthous stomatitis (RAS); may significantly reduce the pain and healing time to RAS ulceration.

Pharmacological Therapy for children under age 12

- Children may experience weight loss, time off of school, difficulty in speaking and eating, and dehydration
- Principles of treatment:
    - Ensure correct diagnosis
    - Ensure underlying conditions are detected and effectively treated
    - Reassure parents and child and explain limitations of treatment
    - Avoid "over-medicalizing" condition (consider no intervention)
    - Teach parents to monitor child's eating and dehydration
    - Nutritional support may be considered in children who refuse to eat during the entire duration of the attack
    - Children under 6 cannot rinse and expectorate effectively; avoid preparations that cannot be swallowed by young children
    - Avoid tetracycline preparations, even as a mouthwash, in children under 12

- Refer to Table 3 for preparation recommendations for children

Table 3: Recommendations for Recurrent Aphthous Stomatitis in children under age 12

First Line	• Benzydamine and local anesthetics • Lidocaine gel preps (Calgel teething gel) may be applied several times a day in small quantities and before meals to improve eating (strength of recommendation A; quality of evidence II-b, III, & IV).
In more severe cases	• Triamcinolone 0.1% in carboxymethylcellulose paste (Adcortyl in Orabase) can be managed only by older children. • Hydrocortisone sodium succinate 2.5mg tablets (Corlan) are safe in children because of their low steroid potency (strength of recommendation A; quality of evidence II-b, III, & IV).

Principles of treatment for HIV-associated ulcers

- Antifungal treatment may be required in conjunction with steroids.
- Biopsy may be indicated to ensure treatable infection (i.e., herpes simplex, cytomegalovirus [CMV]).
- A further immunosuppression with new infections may arise.
- Steroids should be used with caution: prednisolone 40 mg for 4 days, reducing by 5 mg every 2 days until 5 mg, then reducing by 1 mg per day to 0 mg provide rapid relief.
- Intralesional injection delivers high doses of steroids directly to the lesion and avoids long-term systemic adverse effects.

Definitions:

Strength of the Recommendation

A. There is good evidence to support the recommendation that the treatment be specifically considered in the management of recurrent aphthous stomatitis.
B. There is fair evidence to support the recommendation that the treatment be specifically considered in the management of recurrent aphthous stomatitis.
C. There is insufficient evidence to recommend for or against the inclusion of the treatment in the management of recurrent aphthous stomatitis, but recommendations may be made on other grounds.
D. There is fair evidence to support the recommendation that the treatment be excluded from consideration in the management of recurrent aphthous stomatitis.
E. There is good evidence to support the recommendation that the treatment be excluded from consideration in the management of recurrent aphthous stomatitis.

Quality of Evidence

- Category Ia. Evidence is obtained from meta-analysis of randomized controlled trials.
- Category Ib. Evidence is obtained from at least one randomized controlled trial.
- Category IIa. Evidence is obtained from at least one well-designed controlled study without randomization.
- Category IIb. Evidence is obtained from at least one other type of well-designed quasi-experimental study.
- Category III. Evidence is obtained from well-designed non-experimental descriptive studies such as comparative studies, correlational studies, and case control studies.
- Category IV. Evidence is obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Adapted from: United Stated Department of Health and Human Services (U.S. DHHS), Office of Public Health & Science. U.S. Preventive Services Task Force, (1996). Guideline to Clinical Preventive Services, (2nd ed.), Alexandria, VA: International Medical Publishing, Inc.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for selected recommendations (see "Major Recommendations").

The evidence used for this guideline includes evidence from a meta-analysis of randomized controlled trials; at least one randomized controlled trial; non-randomized controlled studies, non-experimental descriptive studies: comparative, correlational, and case control; and expert committee reports or opinions and/or clinical experience of respected authorities.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased incidence, duration, frequency, and severity of recurrent aphthous stomatitis

POTENTIAL HARMS

- Orabase or Benzydamine hydrochloride (HCL) mouthwash: mild stinging

- Triamcinolone 0.1% in carboxymethylcellulose paste (Adcortyl in Orabase) can facilitate overgrowth of Candida; some patients experience allergic reaction.
- Hydrocortisone sodium succinate 2.5 mg (Corlan): systemic, immunosuppressive effects of systemic steroids
- Betamethasone sodium phosphate (Betnesol) mouthwash: allergies to Betnesol, potential for yeast overgrowth
- Betamethasone dipropionate (Diprolene or Temovate) may cause stinging, burning, and secondary Candida infections.
- Amlexanox 5% (Aphthasol) adhesive oral paste: transient local pain, burning, stinging
- Chlorhexadine 0.2% mouth rinse or 1% gel (Peridex): dental deposits, staining of teeth, taste changes, parotitis
- Tetracycline given to pregnant women and young children can permanently stain young children's teeth.
- Fluocinonide (Lidex) may cause atrophy of oral mucosa, burning, itching, or perioral dermatitis
- Thalidomide (Thalomid): severe birth defects, teratogenic, peripheral neuropathy, neutropenia, seizures, dry mouth. (Note: **Restricted use in the United States**)
- Colchicine may affect spermatogenesis; use with caution in childbearing adults.

Pregnancy cautions include:

Lidocaine gel, Orabase, or Peridex – category A
Amlexanox – category B
Chlorhexadine – category B
Betamethasone dipropionate (Diprolene, or Temovate) - category C
Colchicine – category C
Fluocinonide (Lidex) – category C
Thalidomide – category X

Subgroups Most Likely to Experience Harms:

Patients with hypersensitivity to drug class or component of the recommended medications

CONTRAINDICATIONS

CONTRAINDICATIONS

Colchicine is contraindicated in patients with renal, hepatic, cardiac, or blood diseases.

QUALIFYING STATEMENTS

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The tables presented in the original guideline document were not intended to supersede or prevent providers from using their best clinical judgment in the care of an individual patient. The intent is to establish verifiable treatment modalities for individuals with recurrent aphthous stomatitis that will lead to a reduction in number of ulcers, duration, frequency, and severity of pain.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 May

GUIDELINE DEVELOPER(S)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the University of Texas at Austin, School of Nursing. 1700 Red River, Austin, Texas, 78701-1499

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 5, 2004. The information was verified by the guideline developer on May 18, 2004. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug advisory on Colchicine.

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